

REMARKS

Upon entry of the foregoing amendments, claims 18, 25, 27, 28, 30 and 32-34 are currently pending in the present application. Claims 19-24, 26, 29, 31 and 35 have been cancelled without prejudice or disclaimer. Claims 18 and 32 have been amended.

The amendment of claim 18 is in the expectation that the amendments will place this application in condition for allowance and the amendment of claim 32 is in accordance with the cancellation of claim 31. The amendments do not introduce new matter within the meaning of 35 U.S.C. §132. Accordingly, entry of the amendments is respectfully requested.

In view of the following, further and favorable consideration is respectfully requested.

1. Claim Rejection - 35 U.S.C. §102(b)

The Official Action states in the relevant part that claims 18, 19, 21, 22, 25-27 and 31-35 are rejected under 35 U.S.C. §102(b) as being anticipated by Trogolo et al. (U.S. Patent No. 6,296,863).

Applicant traverses this rejection and respectfully submits that claim 18, the single independent claim, has been amended to incorporate all the limitations of previously pending dependent claims 19-24, 26, 29, 32 and 35. Among these dependent claims, claims 20, 23, 24 and 29 are not rejected by the Examiner as anticipated by Trogolo, et al. Accordingly, the basis of this rejection has been removed and the currently pending claims are not anticipated by Trogolo et al.

Therefore, Applicant respectfully requests that the Examiner's rejection based on Trogolo et al. under 35 U.S.C. §102(b) be reconsidered and withdrawn.

2. Claim Rejection(s) - 35 U.S.C. §103(a)

The Official Action states that claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. in view of Burrell et al. (U.S. Patent No. 5,837,275); claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. in view of Pourrezai et al. (U.S. Patent No. 5,685,961); claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. in view of Lawson et al. (U.S. Patent No. 6,579,539); and claims 28-30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trogolo et al. in view of Shikani et al. (U.S. Patent No. 5,762,638).

Applicant respectfully traverses this rejection.

The Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims, which are now incorporated into the amended claim 18. To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U. S. __ (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it

can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR, supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Presently Claimed Subject Matter

The presently claimed subject matter as amended in claim 18 of the subject application, relates to a vascular prosthesis having a particular laminate-type structure as follows:

"A vascular prosthesis for replacement of hollow organs with antibiotic long-term action with a basic structure which defines the form of the prosthesis and which is made of substantially non-absorbable or only slowly absorbable polymer material and of a coating of an absorbable material, with a layer of metallic silver situated on the polymer material and underneath the coating,

wherein the silver layer is a substantially closed layer having thickness of 2500 to 1000 Å, breaks down in the body at a maximum of 5 to 10% per annum, adheres firmly on the polymer material by vapor-deposition and of which silver atoms are impressed into the polymer surface of the basic structure; and

the basic structure is porous made from a textile material, the silver layer leaves the pores open and the absorbable coating layer is an impregnation which seals the pores of the prosthesis and is chosen such that it is absorbed at the latest after four months."

By employing this particular layering structure containing a **metallic** silver layer that is covered by an absorbable polymer coating, which means the silver layer is situated **on** the polymer material and **underneath** the absorbable coating, it leads to an improved releasing rate of silver during a starting time of about 50 days after implantation which is probably due to an activation or corrosion of the metal layer, as described at page 3, paragraphs [0008] & [0009] of the specification. This technical effect is also supported by the Applicant's comparison tests at pages 8-9, paragraphs [0021]-[0023] of the specification.

Further, by employing a vapor-deposition method for forming the metallic silver layer, the silver layer is advantageously adheres firmly to the surface of the polymer material and is in particular anchored in it (see, page 4, paragraph [0009] of the specification).

Trogolo et al.

Trogolo et al. disclose a medical graft containing an inorganic antimicrobial agent that is coated with a tissue compatible material (see, col. 2, lines 10-12). A medical graft with a layer of a metallic/elemental silver is not specifically taught. In contrast to the Examiner's opinion presented in the Official Action, Trogolo et al. only disclose that the graft comprises antimicrobial metal ions, for instance silver cations (see, col. 3, line 66 to col. 4 line 11). No specific teachings are found by Trogolo et al. that said silver cations exist as a particular layer, i.e., a metallic silver layer that is situated

on the polymer prosthesis material but underneath the coating. In contrast, the presently claimed vascular prosthesis comprises a particular layer of **metallic** silver which is situated **on** the polymer material and **underneath** the absorbable coating.

Further, although one could consider that Trogolo et al. teach the coating of the antimicrobial agent, it remains a complete different situation in comparison to the presently claimed subject matter. It has been successfully proved by the inventors of the presently claimed subject matter that such particular layering of a vascular prosthesis leads to an optimized releasing rate for silver. A vascular prosthesis with these features is not disclosed by Trogolo et al.

Furthermore, Trogolo et al. mainly focus on antibiotic zeolites as suitable antimicrobial agents having antimicrobial metal cations (see, col. 4, line 12 to col. 6, line 18). Concerning said zeolites, the release of metal cations in the environment takes place via an ion-exchange. This is completely different releasing mechanism compared to the present vascular prosthesis, and this particular laminate structure of the presently claimed prosthesis contributes to an optimized releasing rate of antimicrobial silver cations in the tissue environment after its implantation in a body.

Furthermore, Trogolo et al. disclose neither of thickness 2500 to 1000 Å of the silver layer, nor of the vapor-deposition by which the silver layer adheres firmly on the polymer material.

As such, Applicant submits that Trogolo et al. fail to teach or suggest all the elements of the presently claimed

vascular prosthesis, and thereby fails to either anticipate or render the presently claimed vascular prosthesis obvious.

Trogolo et al. in view of Burrell et al.

Burrell et al. do not remedy these deficiencies discussed above with regard to Trogolo et al.

Burrell et al. disclose antimicrobial coatings and methods of forming appropriate equipped medical devices and different deposition techniques are specified. The particular layering of the presently claimed vascular prosthesis is not taught by Burrell et al. Merely composite metal coatings of one or more metals or compounds to be released into an environment is described next to a normal metal layering (see, col. 6, line 50 to col. 7, line 28; col. 9, line 25 to col. 11, line 49 of the disclosure). Further, an absorbable polymer coating for the (composite) metal layering is not disclosed by Burrell et al.

Accordingly, Trogolo et al., if combined with Burrell et al., do not teach or suggest all the limitations of the presently claimed subject matter as required by *In re Wilson*. Therefore, the Examiner's rejection based on Trogolo et al. in view of Burrell et al. is respectfully requested to be reconsidered and withdrawn.

Trogolo et al. in view of Pourrezai et al.

Pourrezai et al. do not remedy the deficiencies of Trogolo et al. discussed above.

Pourrezai et al. disclos catheters and other medical devices including plural layers of metals applied to the outer surfaces. However, Pourrezai et al. do not teach any coating of metal layers with an absorbable material, as well as a specific medical device of vascular prosthesis. Pourrezai et al. focus on catheters that are completely different devices than the presently claimed vascular prosthesis. Pourrezai et al. also disclose a different method of silver deposition (see, col. 13, lines 54-63), where the silver deposition is realized by a silver plating solution of silver nitrate. In order to obtain the metal layer, said silver salt is reduced by the aid of a reducer solution containing hydrazine hydrate. In contrast, the silver layer of the presently claimed vascular prosthesis is vapor-deposited onto the polymer surface of the prosthesis and therefore adheres firmly on the vascular prosthesis. Further, it is not necessary to apply a carcinogen compound like hydrazine hydrate which requires additional time consuming purification and rinsing steps.

Accordingly, Trogolo et al., if combined with Pourrezai et al., fail to teach or suggest all the limitations of the presently claimed vascular prosthesis as required by *In re Wilson*. Therefore the Examiner's rejection based on Trogolo et al. in view of Pourrezai et al. is respectfully requested to be reconsidered and withdrawn.

Trologo et al. in view of Lawson et al.

Lawson et al. do not remedy the deficiencies of Trogolo et al. discussed above.

Lawson et al. disclose medical articles with a layer of metallic silver and a hydrogel covering said silver layer, wherein the hydrogel contains an antimicrobial agent. The medical articles are different from the presently claimed subject matter in that it necessarily comprises an additional antimicrobial agent contained in the hydrogel. In contrast, the presently claimed vascular prosthesis dose not necessarily comprises an additional antimicrobial agent. This is due to its optimized releasing rate of silver resulting from the special laminate-type-layering of a metallic silver layer that is underneath an absorbable coating layer. Further, Lawson et al. discloses, as a preferred coating material, polyurethane and focuses mainly on this material, which is obviously a **non-absorbable** material.

Further, importantly, Lawson et al. fails to disclose vapor-deposition to form the silver layer, only disclosing as a preferred method wet deposition, in particular dipping procedures. Wet deposition techniques require a further (pedestrian) step for the manufacture of the silver layered articles, mainly the application of a reduction step (see, col. 2, lines 65-67). In contrast, the presently claimed vascular prosthesis comprises a silver layer that is vapor-deposited onto the prosthesis's surface. This contributes to firm adherence on the prosthesis's surface.

Accordingly, Trogolo et al., if combined with Lawson et al., do not teach or suggest all the limitations of the presently claimed subject matter as required by *In re Wilson*. Therefore the Examiner's rejection based on Trogolo et al. in view of Lawson et al. is respectfully requested to be reconsidered and withdrawn.

Trogolo et al. in view of Shikani et al.

Shikani et al. do not remedy the deficiencies of Trogolo et al. discussed above.

Shikani et al. disclose invasive medical devices in which a polymer has been coated or incorporated with anti-infective and/or anti-inflammatory agents and in which the polymer comprises pharmaceutical compositions that have a delayed or sustained release from said polymer. Shikani et al. do not disclose a metallic silver layer in combination with an absorbable material with the particular laminate-type structure in the presently claimed vascular prosthesis, let alone the vapor-deposition method and the thickness of the silver layer.

Accordingly, Trogolo et al., if combined with Shikani et al., do not teach or suggest all the limitations of the presently claimed subject matter as required by *In re Wilson*. Therefore, Applicant respectfully requests the Examiner's to reconsider and withdraw the rejection based on Trogolo et al. in view of Shikani et al.

**Trogolo et al. in view of any combination of Burrell et al.,
Pourrezai et al., Lawson et al. and Shikani et al.**

In view of the foregoing, Applicant respectfully submit that Trogolo et al. whatsoever combined with any of Burrell et al., Pourrezai et al., Lawson et al. and Shikani et al. fail to teach or suggest all the elements/limitations of the presently claimed vascular prosthesis, and thereby fails to render the presently claimed vascular prosthesis obvious.

Regarding the combination of Trogolo et al. with all other references above, Applicants respectfully submit that the Examiner has not established *prima facie* obviousness in this Office Action. Accordingly, this can be discussed once the Examiner establishes *prima facie* obviousness based on the combination. Applicants respectfully submit that the Examiner's rejection based on the combination, if issued, must satisfy both the requirements also: first, apparent reason to promote one of ordinary skill in the art to combine Trogolo et al. with Burrell et al., Pourrezai et al., Lawson et al. and Shikani et al., in the fashion claimed by the presently pending claims as required by *KSR International Co. v. Teleflex Inc. et al.*; and second, reasonable expectation of success in combining Trogolo et al. with Burrell et al., Pourrezai et al., Lawson et al. and Shikani et al. to reach the presently claimed vascular prosthesis as required by *Amgen Inc. v. Chugai Pharm. Co.* In this regard, Applicants submit that, in view of the forgoing discussion on each reference, there would no apparent reason to combine all those elements disclosed in the five (5) cited references and, if any, one skilled in the art would not have a reasonable expectation of success in combining them.

As such, Trogolo et al., taken alone or in combination with Burrell et al., Pourrezai et al., Lawson et al. or Shikani et al., does not teach, disclose, or render obvious the presently claimed vascular prosthesis in pending claim 18, as well as its dependent claims 25, 27, 28, 30 and 32-34.

Accordingly, Applicant respectfully request the Examiner to reconsider and withdraw the rejection against the presently pending claims.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be patentably distinguishable over the prior art of record. The Examiner is respectfully requested to reconsider and withdraw the outstanding rejections and allow all pending claims 18, 25, 27, 28, 30 and 32-34. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

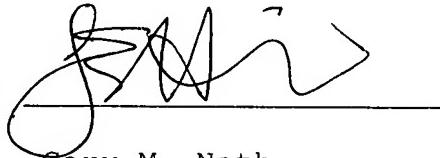
The Examiner is invited to contact the undersigned attorney if it is believed such contact will expedite the prosecution of the application. Also, if the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the below-listed number and address.

Respectfully submitted,

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